

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Starobin et al.
Serial No. 10/625,133
Filed: July 23, 2003
For: *Method and System for Evaluating Cardiac Ischemia Based on Heart Rate Fluctuations*

Confirmation No.: 8270
Group Art Unit: 3762
Examiner: Alyssa M. Alter

Date: August 17, 2007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION IN RESPONSE TO NON-FINAL
OFFICE ACTION DATED MAY 18, 2007**

This is in response to the Official Action of May 18, 2007.

Double patenting.

Claims 1-37 were rejected in the Action on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-17 of U.S. Patent No. 7,123,953 to Starobin (hereinafter "the Starobin patent"). The Action states as follows:

although the conflicting claims are not identical, they are not patentably distinct from each other because Patent '953 discloses the "risk of cardiac arrhythmia" which can be caused by cardiac ischemia. Therefore, it would be obvious to sense cardiac ischemia, a precursor to cardiac arrhythmias, to add in the determination of cardiac or cardiovascular health.

Applicants respectfully disagree. In addition to the differences between screening for risk of cardiac arrhythmia (the Starobin patent) and assessing cardiac ischemia (the current application), the claims of the current application include numerous recitations that are patentably distinct and are not obvious from those of the Starobin patent. As such, the nonstatutory obviousness-type double patenting rejection is improper.

Claim 1 of the Starobin patent and Claim 1 of the current application are

reproduced below (emphasis added):

Claim 1 (the Starobin patent)

1. A method of screening for risk of cardiac arrhythmia in a subject, the method comprising the steps of:

(a) collecting at least one QT interval data set and at least one RR interval data set from the subject during (i) a stage of gradually increasing heart rate, (ii) a stage of gradually decreasing heart rate, or (iii) both a stage of gradually increasing heart rate and gradually decreasing heart rate;

(b) separating fluctuations from slow trends in said at least one QT interval data set and in said at least one RR interval data set to provide QT fluctuations and RR fluctuations;

(c) comparing said QT fluctuations and said RR fluctuations to one another to determine the difference therebetween; and

(d) generating from the comparison of step (c) a measure of risk of cardiac arrhythmia in said subject, wherein a greater difference between QT fluctuations and RR fluctuations indicates greater risk of cardiac arrhythmia in said subject.

Claim 1 (the current application)

1. A method of assessing cardiac ischemia in a subject to provide a measure of cardiovascular health in that subject, comprising said steps of:

(a) collecting a first RR- interval data set from said subject during a stage of gradually increasing heart rate;

(b) collecting a second RR- interval data set from said subject during a stage of gradually decreasing heart rate;

(c) separating fluctuations from a slow trend in said first RR- interval data set;

(d) separating fluctuations from a slow trend in said second RR- interval data set;

(e) comparing said fluctuations of said first RR- interval data set to said fluctuations of said second RR- interval data set to determine a difference between said fluctuation data sets; and

(f) generating from said comparison of step (e) a measure of cardiac ischemia during stimulation in said subject, wherein a greater difference between said first and second data sets indicates greater cardiac ischemia and lesser cardiac or cardiovascular health in said subject.

In particular, the Starobin patent is directed to comparing QT fluctuations and RR fluctuations to one another as recited in Claim 1 of the Starobin patent. The claims of

the current application do not recite QT fluctuations, and as such, are patentably distinct from the claims of the Starobin patent.

Moreover, although the disclosure of the Starobin patent is broad, the current claims are not obvious over the claims of the Starobin patent. Claim 1 of the Starobin patent recites comparing QT fluctuations and RR fluctuations to one another to generate a measure of risk of cardiac arrhythmia in the subject. In contrast, Claim 1 of the current application recites comparing fluctuations of a first RR- interval data set to fluctuations of a second RR- interval data set. Applicants submit that comparing QT fluctuations and RR fluctuations as disclosed in the Starobin patent does not render obvious comparing fluctuations from first and second RR- interval data sets as recited in the current claims.

For at least these reasons, Applicants respectfully request that the double-patenting rejection of Claims 1-37 based on the Starobin patent be withdrawn.

Claim Rejections under 35 U.S.C. § 103(a).

Claims 1-37 were rejected in the Action under 35 U.S.C. § 103(a) as being obvious over U.S. Patent Publication 2003/0130586 to Starobin (now U.S. Patent No. 7,123,953) (hereinafter "the Starobin publication").

Applicants submit that Starobin is not prior art under § 103, and therefore, Applicants request the rejection under § 103 be removed. It is noted that subject matter that is prior art under 35 U.S.C. § 102 can be used to support a rejection under § 103. *See* M.P.E.P § 2141. The relevant portions of § 102 will now be discussed.

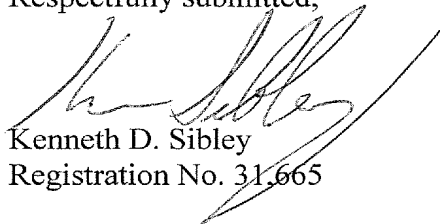
The Starobin publication was filed December 3, 2002 and published on July 10, 2003. The current application was filed July 23, 2003. Accordingly, the Starobin publication was not patented or described in a printed publication more than one year prior to the filing date of the current application and is not prior art under 35 U.S.C. § 102(b). The inventive entity of the Starobin publication is identical to the inventive entity of the current application. Therefore, the Starobin publication is not prior art under 35 U.S.C. § 102(a) or 35 U.S.C. § 102(e). Applicants submit that the remaining subsections of 35 U.S.C. § 102 also do not apply.

For at least these reasons, Applicants submit that the Starobin publication is not

prior art with respect to the current application and request that the rejections under 35 U.S.C. § 103(a) of Claims 1-37 be withdrawn. However, if any rejections based on the Starobin publication are maintained, Applicants respectfully request that the statutory grounds under which the Starobin publication is alleged to be prior art be specifically pointed out in any subsequent Official Action.

It is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,

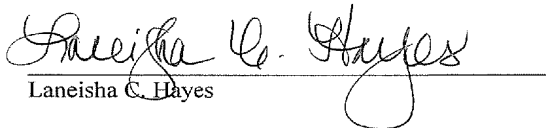


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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on August 17, 2007.



Laneisha C. Hayes